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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,236	07/12/2004	Thomas Beckert	253871US0PCT	3554

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/501,236	BECKERT ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-12 and 17* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/01/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement filed 02/09/09 and the Response to Non-Responsive Amendment filed 05/27/09 is acknowledged.

Applicant's election with traverse of Group I (claims 1-8 and 10-12) in the reply filed on 09 February 2009 is acknowledged. The traversal is on the ground(s) that "Claims 1-12 have been previously searched and examined and that a serious search burden is not created by new claim 17 and the Office has indicated both groups are pharmaceutical formulations". This is not found persuasive because as stated in the Restriction Requirement (dated 01/08/09), the Group II invention is distinct from the Group I invention multifold. Group II does not require: (1) the intermediate layer of Group I which comprises 40 to 100% by weight free-radical polymerized units of C1 to C4 alkyl esters of acrylic or methacrylic acid; (2) does not require the specific binder (vinylpyrrolidone vinyl acetate copolymer) of the Group I invention; (3) does not require that the outer envelope be a capsule and (4) does not require a multiparticulate form having at least two different types of pellets as is claimed in the Group I invention. While both groups are pharmaceutical formulations, the features and elements of the respective formulations are distinct each from the other and are capable of supporting a separate patent within the art. Moreover, both groups would require separate searches in both patent- and non-patent databases and there is no expectation that the searches would be coextensive in scope. This creates a serious search burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim 17 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09 February 2009.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The 35 U.S.C. §112, second paragraph rejection of claims 1 and 8 has been withdrawn; (2) The 35 U.S.C. §103(a) rejection over Ulmius (U.S. Pat. No. 5,643,602) has been withdrawn.

Claims 1-8, 10-12 and 17 are pending in this action. Claims 1 and 8 have been amended. Claims 9 and 13-16 have been cancelled. Claim 17 is withdrawn (non-elected invention). Claims 1-8 and 10-12 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckert *et al.* (hereinafter "Beckert") (WO 01/68058) (U.S. equivalent Pat. No. 6,632,454).

Beckert ('058) teaches a multilayer pharmaceutical product that substantially comprises a) a core containing a pharmaceutically active substance, b) an inner coating consisting of a copolymer or a mixture of copolymers that are composed of 85 to 98 wt.% of radically polymerized C_1 to C_4 alkyl esters of the acrylic or methacrylic acid and 15 to 2 wt.% of

meth(acrylate) monomers with a quaternary ammonium group in the alkyl group, and c) an outer coating consisting of a copolymer that is composed of 75 to 95 wt.% of radically polymerized C_1 to C_4 alkyl esters of the acrylic or methacrylic acid and 5 to 25 wt.% of meth(acrylate) monomers with an anionic group in the alkyl group. The product is used for producing a pharmaceutical product that releases the active substance contained therein according to the USP release test, at pH 1.2 during 2 hours and subsequent rebuffering to pH 7.0, by less than 5% after 2.0 hours after start of the test and by 30 to 80% % after eight hours after start of the test (Abstract). The active substance can be budesonide. The dosage form includes a binder such as collidon 25 as well as an internal coat of Eudragit RS and RL and an external enteric coating of Eudragit FS (Example 1 - pages 16-18).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Beckert.

* * * * *

Response to Arguments

Applicant's arguments filed 10/01/08 have been fully considered and were found to be partially persuasive.

- **Rejection under 35 USC § 112:**

Applicant argued, "Claims 1 and 8 are amended for clarity."

Applicant's arguments were persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claims 1 and 8 has been withdrawn.

- **Rejection under 35 USC § 103(a) over Beckert (WO 01/68058):**

Applicant argued, "Beckert does not describe binding the active, budesonide, with the binder but rather applies the binder and active separately. Beckert does not suggest providing an inner layer where the active is bound in a binder as in claim 1."

Applicant's arguments have been considered but were not deemed persuasive. As pointed out by Applicant, the arguments raised concern the method of manufacturing the pharmaceutical formulation, whereas the instant invention is drawn to a product and not a method of making. In particular Applicants argued regarding how the active ingredient is bound within the binder, such as by the spray coating of Beckert versus the melt extrusion or dispersion of the instant invention. It is the position of the Examiner that the limitation of "the active ingredient bound in a binder" in claim 1 does not distinguish over the formulation of Beckert. The argument that Beckert uses a spraying technique of adding the active ingredient onto the binder does not render a patentable distinction over the instant invention since there would be sufficient contact of the binder with the active ingredient (budesonide) (such as by permeation) in Beckert so as to read on Applicant's claim 1 limitation of the "active ingredient bound in a binder". Moreover, the manner or process in which the encapsulation of the drug in the binder is achieved is not pertinent to the product claims of the present invention. A product is being claimed herein and it is the patentability of the product that must be established. There is no requirement in the claims that the binding of drug within the binder be by a melt extrusion or dispersion technique. Furthermore, there is no requirement in the instant claims regarding the level or degree in which the active agent should be bound within the binder. No level of encapsulation has been recited which would distinguish over the formulation of Beckert. The

instant claim merely recites "active ingredient bound in a binder". This limitation reads on the drug-binder contact of Beckert, absent a showing of evidence to the contrary.

Applicant argued, "Kollidon 25 is not an anionic polymer but a polyvinylpyrrolidone polymer which is neutral and therefore not a polymer or copolymer with acidic groups. Budesonide formulations have the problem of low solubility and providing a binder that is a polymer or copolymer with acidic groups provides that stability."

These arguments have been considered but were not deemed persuasive. It is agreed that Kollidon 25 is a polyvinylpyrrolidone polymer (and not an anionic polymer). However the teachings of the prior art are not limited to the examples disclosed therein. The reference as a whole must be taken into consideration. In this instance, the prior art is well aware of combining a binder component with the active agent (budesonide) and is well aware of providing a structured formulation as is presently claimed herein. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., stability and/or low solubility problems encountered with budesonide) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note in particular that suitable drugs employed by Beckert (U.S. 6,632,454) include those having "adequate stability" such as "budesonide" (see col. 3, lines 50-59 of '454). Thus, the reference is suggestive of the same objective (i.e., stability) as that sought and desired by Applicant.

- **Rejection under 35 USC § 103(a) over Ulmius (U.S. 5,643,602):**

Applicant argued, "In example 1, Ulmius uses Aquacoat® ESD as a binder for budesonide. Aquacoat® ESD is not an anionic polymer but ethylcellulose which is a neutral polymer. (see attached publicly available information concerning Aquacoat® ESD). There is also no inner coatinglayer in Ulmius. Therefore Ulmius neither describe nor suggests a polymeric binder nor the layer composition as claimed."

Applicant's arguments have been considered and were deemed persuasive based on the structural difference in the layering disclosed by Ulmius. Accordingly, the 35 U.S.C. §103(a) rejection over Ulmius has been withdrawn.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claim 17 drawn to an invention nonelected with traverse in the reply filed on 09 February 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

August 17, 2009